UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/769,962	02/02/2004	Darin G. Schaeffer	10703/042	9118

7590 09/07/2007

BRINKS HOFER GILSON & LIONE
ONE INDIANA SQUARE, SUITE 1600
INDIANAPOLIS, IN 46204

EXAMINER	
ALI, SHUMAYA B	
ART UNIT	**PAPER NUMBER**
3771	

MAIL DATE	DELIVERY MODE
09/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/769,962	SCHAEFFER ET AL.	
	Examiner	Art Unit	
	Shumaya B. Ali	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 6/22/06.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1 and 3-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1,3,4,6-9,12-31 is/are rejected.

7)☒ Claim(s) 5,10,11 and 32 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

In response to the office action dated 3/22/07, Applicant has amended claims 12,15,22, and 30 and entered new claim 32. Claim 2 was previously cancelled. Currently claims 1, and 3-32 are pending in the instant application.

Response to Arguments

Applicant's arguments filed on 6/22/07 have been fully considered but they are not persuasive.

With respect to claim 1, applicant argues that Lester does not teach selectable attachment and detachment of the flange from the proximal end of the tube (see page 8, lines 26-30). However, Examiner contents since the claim is not requiring a complete detachment of the flange from one position to another, the sliding movement of Lester's flange reads on the claimed limitation, see reasoning provided below for claim 1.

With respect to claim 30, applicant argues that newly added limitation, "following insertion of said distal end portion" is not taught by Lester (see page 11, lines 15-28 and page 12, lines 1-14). Since Lester's flange is slideable, the tube can be completely slid out of the flange by adjusting bolt 18. Thus, the flange can be engaged flowing insertion of the distal end portion into the trachea. Thus, Lester teaches newly added limitation of claim 30

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1,3, and 22-29 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lester US 5,928,198.

As to claim 1, Lester discloses a tracheotomy tube (fig.1, 10) comprising: a hollow tubular body having a proximal end portion (proximal end is away from the body/toward flange

15), a distal end portion (opposite end of the proximal) and a curved portion intermediate said proximal and distal end portions (fig.1 depicts a curved portion between the distal and proximal end of the tube); and a flange (15) situated at said proximal end portion, said flange being capable of selective attachment to said proximal end portion and detachment therefrom, said flange extending radially from said proximal end portion when attached thereto (col.2 lines 18-40). Even though Lester lacks explicit teachings of selective attachment and detachment of the flange as claimed, Lester's teachings of a flange that can be adjusted to place the flange at a various combination of locations along the tube render selective attachment and detachment of the flange as claimed obvious. Lester discloses a flange that has a flexible plate to which two semi-circular arms are attached and hinged with one another. Lester further discloses the arms can be clamped hinged with one another to lock the flange at any location along the tube (see col.2 lines 32-38). Thus, movement of Lester's flange from a first to second locations along the tube would inherently require one of ordinary skill in the art to detach the arms at the first location, and then reattach the arms at the second location. Furthermore, Lester's teaching of a flange with long arms at the proximal end of a tube would inherently prevent any radial extending of the tube. Therefore, it would have been obvious to one of ordinary skill in the art to derive the intended use of the flange as claimed using the flange of Lester.

As to claim 3, Lester lacks wherein said flange is attachable to said tube by a snap-fit. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to attach the flange using known attachment means.

As to claim 22, Lester discloses a device for precutaneous insertion into the trachea of a patient, comprising: a tracheotomy tube (10) having a longitudinal passageway (fig.1) there

through, said tracheotomy tube having a distal end (11) portion precutaneous insertable into said trachea and a proximal end (toward 12) portion exterior to the trachea when said distal end portion is inserted; said tracheotomy tube further having a radially extending flange (see labeled fig.1, attached below). Lester further teaches said flange is attachable to said proximal end portion of the tracheotomy tube after said distal end portion has been inserted into the trachea so that the flange can be locked at any location along the trachea tube as applied for claim 1. Lester further discloses a dilator (2) positionable within said longitudinal passageway of said tracheotomy tube (fig.1) for dilating an opening in said trachea for insertion of said tracheotomy tube; and a locking assembly (28,30,31) for locking the tracheotomy tube to the dilator during insertion of said tracheotomy tube into the trachea.

As to claim 23, Lester discloses wherein said locking assembly comprises a securement member (30,31) associated with the dilator, said securement member engageable with a complementary member (32) on said tracheostomy tube.

As to claim 24, Lester discloses wherein said locking assembly further comprises a stop (28) member disposed on an outer surface of said dilator, said stop member engaged with said dilator such that substantial axial movement of said stop member along said dilator is prevented when an axial force is applied to said stop member (see fig.3), said stop member positioned on said outer surface and engageable with said securement member and said complementary member for preventing excess penetration of tracheostomy tube into the trachea (see figs.1 and 3).

As to claim 25, Lester discloses wherein said stop member comprises an annular ring (29) integral with said dilator.

As to claim 26, Lester discloses wherein said stop member comprises an annular ring fitted on the outer surface of said dilator (see fig.2)

As to claim 27, Lester discloses wherein said complementary member comprises a collar (12) integral with said tracheostomy tube.

As to claim 28, Lester discloses wherein said complementary member comprises a collar fitted on an exterior surface of said tracheostomy tube (see fig.3).

As to claim 29, Lester lacks wherein said securement member comprises a cap member having one or more screw threads engageable with said complementary member for locking said tracheostomy tube to said dilator, however, Lester teaches snap fitted locking means. Since Applicant has not stated why a specific type of locking means are critical to the invention in terms of providing a specific function or solving a stated problem, one of ordinary skill in the art would consider Applicant's invention to perform equally well with the snap fitted locking means taught by Lester because the ability of the locking means to hold the tube in a stable position would not be affected by the type of locking means. Therefore, it would have been an obvious matter of design choice to modify Lester to obtain the invention as specified in claim 29.

Claims 4,6, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lester US 5,928,198 in view of Montgomery US 4,269,184

As to claim 4, Lester discloses wherein said flange includes a cut-away portion (see labeled fig.1, attached below), collar (12), however, lacks wherein said collar having a groove, and said groove being cooperatively sized and shaped to mate when said flange is attached to said tube, however, Montgomery teaches groves on an endotracheal tube can serve to secure the apertures face plate 20 (flange) (see col.3 lines 17-20). Therefore, it would have been obvious to

one of ordinary skill in the art at the time the invention was made to provide grooves on the tube of Lester in order to secure the flange as taught by Montgomery.

As to claim 6, Lester discloses wherein said collar is integral with the hollow tubular body (see fig.1)

As to claim 7, Lester lacks wherein said collar includes one or more barbs for attaching the collar to said hollow tubular body. However, barb structures are disclosed, as an alternative species to the integral collar of claim 6, which is also taught by Lester, therefore would not require an additional structure, i.e. barbs for attachment to the tubular body. Therefore, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have an integral collar with does not require any attachment means, or barbs attaching the collar to the tubular body because Applicant has not disclosed that "one or more barbs" provide an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with integral attachment of the collar taught by Lester because the function of the tube when providing tracheostomy would not be affected by how the collar is attached to the tube.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lester US 5,928,198 in view of Fauza US 6,612,305B2

As to claim 8, Lester lacks removable inner cannula insertable in said hollow tubular body. However, Fauza teaches inner cannula (fig.2, 5) which can be removed in case of severe acute obstruction of it, for example by mucous secretions, allowing for immediate establishment of air flow thought the outer tube, and for easier cleaning of the inner tube (see col.3 lines 65-68,

col.4 lines 1-3). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the tube of Lester with inner cannula as a matter of design choice because it is known in the art to have tracheostomy tube with inner and outer cannula as taught by Fauza, and furthermore, it is also known in the art that one of ordinary skill in the art would choose a tracheostomy tube with an inner and outer cannula so that the outer cannula can be placed at a fixed position with respect to patient's trachea while inner cannula can be used for guiding surgical instrument, furthermore, if the surgery required continuous rinsing of the tube due to mucous secretion, then it is convenient to just pull out the inner tube while keeping the outer cannula fixed in the patient, this way the surgeon does not have to repeat the steps of placing the tube in the patient every time the tube needed a rinse.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lester US 5,928,198 in view of Ranford et al. US 4,235,229

As to claim 9, Lester lacks wherein said hollow tubular body includes an inflatable cuff surrounding a part of said distal end portion; said tracheostomy tube further comprising an inflation line connecting said cuff to a source of an inflation fluid, however, Ranford teaches inflatable cuff (fig.1, 21) that can be inflated by inflation line (fig.1, 22) to provide a seal between the tracheostomy tube and the patient's trachea (see col.2 lines 60-66). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the tube of Lester with an inflatable cuff with an inflation line so that the cuff can be inflated and doing so would provide a seal between the tube and the patient's trachea as taught by Ranford.

Claims 12-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lester US 5,928,198 in view of Hazard US 5,058,580.

As to claim 12, Lester in figures 1 and 2 discloses an insertion device comprising a tracheostomy tube (10) and a loading dilator (2), the tracheostomy tube having a longitudinal bore (see fig.1); the loading dilator having a larger-diameter stepped proximal portion (28) and a smaller diameter distal having a generally cylindrical profile (23) and hiving a tapered at its distal end (24), the smaller-diameter distal portion being sized to be insertable through the longitudinal bore of said tracheostomy tube such that said tapered distal end extends axially beyond the tapered distal tip of the tracheostomy tube (see fig.1), the tracheostomy tube having a proximal end and further comprising a stop portion (14) at said proximal end for engaging a distal portion of the larger-diameter stepped portion of the dilator to limit axial movement of the loading dilator through the tracheostomy tube (see fig.1). Lester however lacks the tube has a tapered distal end. However, Hazard teaches a tracheostomy tube with a tapered distal end (see fig.4, 32). Hazard teaches the tapered end provides smooth transition of the obturator (see col.5, lines 15 and 16). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Lester in order to provide a tracheostomy tube with a tapered distal end for the purposes of allowing smooth transition of the dilator as taught by Hazard.

As to claim 13, Lester discloses wherein said stop portion comprises a collar (12) provided at said proximal end of said tracheostomy tube.

As to claim 14, Lester discloses wherein said stop portion comprises a larger-diameter proximal end portion of the tracheostomy tube (see fig.1).

As to claim15, Lester as modified teaches wherein said tapered distal end of said dilator is complementary to the tapered distal tip of the tracheostomy tube such that a generally smooth conical insertion tip is defined thereby (see fig.1).

As to claim 16, Lester discloses wherein said generally smooth conical insertion tip has a profile sufficient for dilating an opening in the body of a patient for insertion of said tracheostomy tube (col.2, lines 40-56, col.3, lines 7-27).

As to claim 17, Lester discloses wherein said larger-diameter stepped proximal portion of the dilator comprises a gripping surface (28).

As to claim 18, Lester discloses wherein said gripping surface is formed from one or more polymers (col.1, line 55).

As to claim 19, Lester discloses wherein said gripping surface is formed from a member selected from the group consisting of lower durometer urethanes, thermoplastic rubbers, thermoplastic elastomer and non-thermoplastic elastomer (col.1, line 55).

As to claim 20, Lester discloses wherein said dilator larger-diameter stepped proximal portion and smaller diameter distal portion comprise integral molded components (see fig.2).

As to claim 21, Lester discloses wherein said larger-diameter stepped proximal portion of said dilator includes a longitudinal passageway, and a portion of said smaller diameter distal portion is securely received within said longitudinal passageway.

Claims 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lester US 5,928,198 in view of Rutter US 7,140,369B2.

As to claims 30 and 31, Lester lacks a detailed description of the claimed steps, however discloses structural limitations required to perform the method steps (see above rejection cited

for claim 1). Lester further lacks the step of trimming an excess portion of said proximal end portion of said tubular body. However, Rutter teaches that the trimming proximal end of the tracheal tube is known in the art for accommodating the size of both adult and child patient (see col.4 lines 5-10). Therefore, it would have been obvious to one of ordinary skill in the art to incorporate the trimming step as claimed to the step of Lester for the purposes of accommodating the intended use of the tube for various size patient, i.e., adult/child, as taught by Rutter. With respect to "following insertion of said distal end portion," it would have been obvious to adjust screw (18) to slide the tracheal tube completely out of the flange and re-engage it back to the proximal portion after the distal end is inserted in the trachea. Thus, the method steps as cited in claims 30 and 31 would have been obvious result of using the apparatus of Lester as modified by Ruttter.

Allowable Subject Matter

Claims 5,10,11, and 32 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-W-F 8:30am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

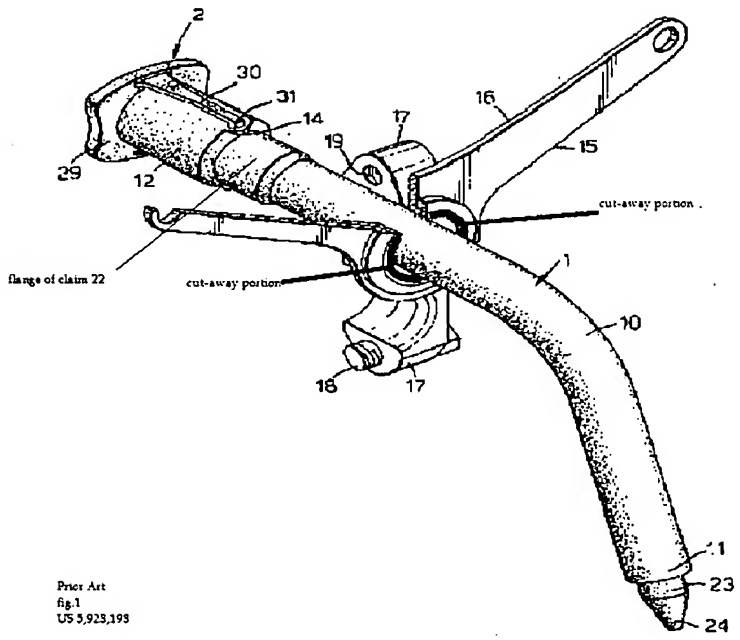
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

8/31/07

Shumaya B. Ali
Examiner
Art Unit 3771

JUSTINE R. YU
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

9/4/07



Prior Art
fig.1
US 5,925,193

8/3/07